In the

# United States Court of Appeals

## For the Seventh Circuit

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No. 12-3342

WESTMORELAND COUNTY EMPLOYEE RETIREMENT SYSTEM,

*Plaintiff-Appellant*,

*v.*

ROBERT L. PARKINSON, JR., *et al.*,

*Defendants-Appellees*.

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Appeal from the United States District Court for the Northern District of Illinois, Eastern Division.
No. 10 C 6514 — **John J. Tharp, Jr.**, *Judge*.

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ARGUED APRIL 22, 2013 — DECIDED AUGUST 16, 2013

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Before WOOD, TINDER, and HAMILTON, *Circuit Judges*.

WOOD, *Circuit Judge*. This is a shareholder derivative suit arising out of the protracted, and ultimately unsuccessful, efforts of Baxter International, Inc., to fix various problems with a medical device called the Colleague Infusion Pump. Westmoreland County Employee Retirement System (Westmoreland) alleges that Baxter's directors and officers breached their fiduciary duties by "consciously

disregard[ing] their responsibility to bring Baxter into compliance with [a 2006] Consent Decree and related health and safety laws." This breach, it contends, caused Baxter to lose more than $550 million after an FDA-mandated recall of the Colleague Infusion Pumps in 2010. Westmoreland's problem is that it did not first ask Baxter's board of directors to pursue the claims it advances here; it alleges that it should be excused from the demand requirement because of futility. The district court concluded that Westmoreland failed adequately to plead demand futility, as required by Federal Rule of Civil Procedure 23.1(b)(3) and Delaware substantive law, and solely on that basis dismissed the complaint. We reverse.

**I**

We draw the following facts from Westmoreland's amended complaint. In doing so, we bear in mind the fact that the adequacy of its pleadings is measured by federal law—in particular, Rule 23.1. See *Kamen v. Kemper Financial Servs., Inc.*, 500 U.S. 90, 96 (1991); 7C CHARLES ALAN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE §§ 1831, 1836 (3d ed. 2007). The function of the demand futility doctrine, however, is a matter of substance, not procedure. *Kamen*, 500 U.S. at 96. Thus, for instance, although federal law governs the degree of detail that the plaintiff must furnish when it gives its "reasons for not obtaining the action or not making the effort," see Rule 23.1(b)(3)(B), state law will determine whether those reasons are sufficient.

In the mid-1990s, Baxter began manufacturing and selling a product called the Colleague Infusion Pump (the Pump), an electronic medical device used to deliver

intravenous fluids to patients. The Food and Drug Administration (FDA) closely regulates the medical device industry and requires that companies comply with "current good manufacturing practices" and "quality system regulations," see 21 C.F.R. Part 820, when manufacturing such medical devices. Between 1999 and 2005, the Pumps were already suffering from a range of defects, some relating to the manufacturing process and others to flaws in the machinery. The FDA discovered some of these problems during its inspections of Baxter's facilities. The agency sent Baxter a series of warning letters in which it detailed Baxter's failure to bring its manufacturing process into compliance with quality-control standards, but Baxter's response was not satisfactory. In October 2005, the FDA took the drastic step of filing a complaint in federal court seeking forfeiture of all Baxter-owned Colleague Infusion Pumps.

On June 29, 2006, the FDA and Baxter entered into a Consent Decree of Condemnation and Permanent Injunction (Consent Decree), which the court approved. Baxter agreed to stop manufacturing and distributing all models of the Pump within the United States, and it committed to bringing the approximately 200,000 Pumps already in the hands of health care professionals "into compliance with the [Federal Food, Drug, and Cosmetic] Act, its implementing regulations, and this decree." The Consent Decree did not set a deadline for Baxter to complete these remedial efforts, but it required Baxter to develop and implement a Comprehensive Action Plan within a matter of weeks. If at any time the FDA determined that Baxter "failed to comply with any provision of [the] decree, or … violated the Act or its regulations, or that additional corrective actions [were] necessary to achieve compliance[,]" the Consent Decree

authorized the Agency to take "any … corrective actions [it] deem[ed] necessary," including ordering a recall of the Pumps at Baxter's sole expense.

Over the next several years, Baxter devoted significant attention and resources to the task of fixing the Pumps. Company records show that the full board of directors discussed the Pumps at least 28 times between 2006 and 2010, while Baxter's Audit and Public Policy Committees reviewed Pump-related matters at least 19 and 13 times, respectively. During these meetings, Baxter's directors were regularly apprised of "ongoing dialogue with the [FDA]" and "recent meeting[s] [with Agency officials] … concerning proposed remediation plans." The company also expended considerable resources on its remedial efforts, at least at first. From 2005 to 2007, it recorded charges and other costs totaling $185 million related to fixing the Pumps and another medical device that was subject to the Consent Decree. During the first three quarters of 2008, Baxter recorded another $125 million in charges related to the Pumps. But this spending tapered off: in the fourth quarter of 2008, Baxter did not record any charges related to the Pumps, and in 2009, the company spent a relatively modest $27 million. Westmoreland's complaint does not indicate how much, if any, Baxter spent in the first part of 2010.

Despite these efforts, problems with the Pumps persisted, and FDA officials grew increasingly frustrated with Baxter's unsuccessful remedial efforts. According to FDA enforcement officials, whose declarations Westmoreland has submitted along with its Complaint:

> the FDA consistently and repeatedly informed Baxter, during face-to-face meetings, on con-

> ference calls, and in writing, that its Colleague remediation efforts were insufficient and that Baxter's timeline for remediating the Colleague was unacceptable because the Colleague, at all times, remained a violative device that posed significant and potentially deadly health risks to patients receiving treatment using the Colleague pump in the United States.

Because each new "fix" that Baxter devised "creat[ed] additional, significant problems with the Colleague pumps" (*e.g.*, battery and display failures, and diagnostic, software, and registry errors) the FDA informed Baxter at a November 25, 2008 meeting that Baxter would be required to submit clinical data to the FDA as part of its next "510(k) submission." This filing was a critical part of the remedial process, but from late 2008 through early 2010, Baxter failed to generate clinical data (or even take preliminary steps necessary to set up such clinical trials) as instructed. The company also "continued to experience numerous internal quality deficiencies," in violation of 21 C.F.R. Part 820. Officials warned that these shortcomings would undermine the Agency's confidence "in Baxter's processes for collection, verification, and validation of data submitted in a 510(k)." Throughout 2009, the FDA repeatedly informed Baxter that its "timeline for complying with the Consent Decree was unsatisfactory." By late that year, it became "clear within the FDA that Baxter had failed to take the appropriate and timely corrective actions to remediate the violative Colleague pumps … or to improve [its] quality systems to a level that would comply with the … Consent Decree."

As these events were proceeding behind the scenes, company officials told investors that Baxter was "moving down a path where we [are] hopeful that we can launch our next generation platform" (a new device called the Sigma Pump) "in the not-too-distant future." On a September 2009 conference call, Baxter's CEO explained to investors that the Colleague Infusion Pump was an "old device" that lacked "a lot of the technology that's represented in many of the [newer] devices." Although remedial efforts would continue, he said, the time was coming when Baxter would "reassess where we allocate our promotional focus in our resources." On April 8, 2010, Baxter submitted a revised timeline for its response to the Pump's problems to the FDA. According to the new schedule, Baxter would begin the latest round of corrections in May 2012; the company anticipated completing these repairs in 2013.

The FDA found this proposal unacceptable and ended the languishing remedial effort. Invoking its power under the 2006 Consent Decree, it ordered Baxter to recall and destroy all Colleague Infusion Pumps then in use in the United States; to reimburse customers for the value of the recalled device; and to assist in finding replacement devices for these customers. This was the first time the FDA had ever ordered a medical device company to pay a refund to customers. Baxter's stock price fell by more than 5% after the announcement, and the company later recorded a pre-tax charge of $588 million to account for the estimated costs of the recall.

At that point, Westmoreland brought this shareholder derivative action on behalf of Baxter against thirteen "Director Defendants," including CEO and Chairman of the

Board Robert L. Parkinson, Jr., and five non-director "Officer Defendants," alleging breach of fiduciary duty in connection with the Colleague Infusion Pump remedial effort. Although the complaint recites the entire troubled history of the Pump, the relevant period for Westmoreland's claims is late 2008 through May 3, 2010, which is when the defendants allegedly "consciously disregarded their responsibility to bring Baxter into compliance with the Consent Decree and related health and safety laws." All of the Director Defendants were on Baxter's board during this period, and at the time Westmoreland filed its complaint, these thirteen people continued to comprise the entirety of the board. Westmoreland's complaint also alleges wrongdoing in connection with several unrelated matters, but these claims are no longer part of this controversy.

Westmoreland did not file a pre-suit demand with Baxter asking the directors to initiate this action (against themselves) on the corporation's behalf. It skipped this step because, it contends, such a demand would have been futile. Citing Federal Rule of Civil Procedure 23.1(b)(3), the defendants filed a motion to dismiss, arguing that Westmoreland had not "alleged with particularity facts sufficient to excuse demand under Delaware law." The district court granted the motion. Applying the demand futility test announced in *Aronson v. Lewis*, 473 A.2d 805 (Del. 1984), the court concluded that Westmoreland failed to meet its burden of showing that demand would have been futile, because Westmoreland failed to allege facts that would create a reasonable doubt (1) that "the board is disinterested in the lawsuit" or (2) that "the challenged transaction was otherwise the product of a valid exercise of business judgment." This appeal follows.

## II

We review *de novo* the district court's determination that Westmoreland's allegations failed to meet the requirements of Rule 23.1 and thus that its action had to be dismissed. *In re Abbott Laboratories Derivative Shareholders Litigation*, 325 F.3d 795, 803 (7th Cir. 2003). The defendants maintain that *Abbott Labs* "did not adopt and apply a *de novo* standard of review" because there (*id.* at 803) we cited an earlier demand futility case, *Starrels v. First National Bank of Chicago*, 870 F.2d 1168 (7th Cir. 1989), in which we applied an abuse-of-discretion standard. See also Petition for Writ of Certiorari at 17 n.4, *UBS Financial Serv. Inc. of Puerto Rico, et al., v. Unión de Empleados de Muelles de Puerto Rico PRSSA Welfare Plan, et al.*, 2013 WL 1400213 (No. 12-1208) (question presented is whether the First Circuit erred by reviewing a Rule 23.1 determination *de novo* rather than for abuse of discretion, as allegedly done in other circuits), *cert. granted*, 133 S. Ct. 2857 (June 24, 2013). The *UBS* petition, however, overreads our *Abbott Labs* decision insofar as it assumes that we were reviewing for abuse of discretion. It relies on our citation of *Starrels*, but we referred to S*tarrels* only for the uncontroversial proposition that appellate review generally is deferential "except on questions of law," *Abbott Labs*, 325 F.3d at 803. Our holding in *Abbott Labs* rested on our analysis of the law, for which, we noted, "[a]ppellate review is plenary." *Id.* at 803. We considered holding this case for *UBS*, but we have concluded that in this instance the standard of review is not outcome-determinative: whether the Supreme Court endorses the *de novo* standard or abuse-of-discretion, we would conclude that it was error to dismiss Westmoreland's complaint.

Federal Rule of Civil Procedure 23.1 requires a plaintiff bringing a shareholder derivative action to state with particularity "any effort by the plaintiff to obtain the desired action from the directors or comparable authority [and] the reasons for … not making the effort." Whether the content of the statement suffices to permit the shareholder to proceed with the litigation, however, depends on state substantive law. *Robert F. Booth Trust v. Crowley*, 687 F.3d 314, 316-17 (7th Cir. 2012) (citing *Kamen, supra*). In our case, because Baxter is incorporated in Delaware, Delaware law determines whether Westmoreland may litigate derivatively on Baxter's behalf. *Id.*

Under that law, plaintiffs like Westmoreland must make a pre-suit demand of the board of directors, unless "under the particularized facts alleged, a reasonable doubt is created that: (1) the directors are disinterested and independent [or] (2) the challenged transaction was otherwise the product of a valid exercise of business judgment." *Aronson*, 473 A.2d at 814. The test is "in the disjunctive[:] if either prong is satisfied, demand is excused." *Brehm v. Eisner*, 746 A.2d 244, 256 (Del. 2000). Before the district court, Westmoreland argued both that a majority of the current directors are "not disinterested" and that the challenged conduct was not a valid exercise of "business judgment"; in this court, Westmoreland appears to focus only on the second branch of the test. It urges that a finding of demand futility is compelled by our decision in *Abbott Labs*. 325 F.3d at 807-09 (holding that although plaintiffs failed to plead specific facts casting doubt on disinterestedness and independence, they succeeded in creating reasonable doubt that the challenged conduct was the product of valid business judgment).

The business judgment rule establishes "a presumption that in making a business decision the directors of a corporation acted on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the company." *Gantler v. Stephens*, 965 A.2d 695, 705 (Del. 2009) (quoting *Aronson*, 473 A.2d at 812). This standard is "an acknowledgement of the managerial prerogatives of Delaware directors," *id.* at 812, and the parties do not dispute that directors ordinarily enjoy wide latitude in managing a corporation's affairs. See *In re Caremark Intern. Inc. Derivative Litigation*, 698 A.2d 959, 967 (Del. 1996) (emphasizing that "wrong" or "stupid" board decisions generally "provide[] no ground for director liability").

But there are important limits to directors' insulation from personal liability. If a director breaches the fiduciary duty of loyalty—which requires "conduct that is qualitatively different from, and more culpable than, the conduct giving rise to a violation of the fiduciary duty of care (*i.e.*, gross negligence)"—the business judgment rule affords no protection. *Stone v. Ritter*, 911 A.2d 362, 367 (Del. 2006). The fiduciary duty of loyalty "is not limited to cases involving a financial or other cognizable fiduciary conflict of interest," but also "encompasses cases where the fiduciary fails to act in good faith." *Id.* at 370. Where "directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities, they breach their duty of loyalty by failing to discharge that fiduciary obligation in good faith." *Id*. Or, put slightly differently, "the intentional dereliction of duty or the conscious disregard for one's responsibilities [constitutes] bad faith conduct, which results in a breach of the duty of loyalty." *McPadden v. Sidhu*,

964 A.2d 1262, 1274 (Del. Ch. 2008); see also *In re Massey Energy Co.*, C.A. No. 5430-VCS, 2011 WL 2176479, at *20 (Del. Ch. May 31, 2011) ("[A] fiduciary of a Delaware corporation cannot be loyal to a Delaware corporation by knowingly causing it to seek profit by violating the law.").

In this case, the question of demand futility hinges on whether the defendants' actions (or, more accurately, the defendants' considered inactions) amount to "bad faith" under Delaware law. See *Aronson*, 473 A.2d at 813 ("[A] conscious decision to refrain from acting may nonetheless be a valid exercise of business judgment and enjoy the protections of the rule."). If Westmoreland has pleaded enough to show with the necessary particularity how (in its view) the defendants acted in "bad faith," such that they breached their duty of loyalty to Baxter, the alleged conduct would fall into the narrow range of activity that falls outside the scope of the business judgment rule. Westmoreland would then be permitted to proceed with this suit, because Delaware law excuses failure to make a pre-suit demand when a reasonable doubt exists that the challenged conduct was "the product of a valid exercise of business judgment." *Id.* at 814. In this connection, it is worth emphasizing that "[t]he totality of the complaint's allegations need only support a *reasonable doubt* of business judgment protection, not 'a judicial finding that the directors' actions are not protected by the business judgment rule.'" *Abbott Labs*, 325 F.3d at 809 (quoting *Grobow v. Perot*, 539 A.2d 180, 186 (Del. 1988)).

**III**

So let us take a closer look at Westmoreland's allegations. While acknowledging that Baxter officials expended

considerable company resources in an effort to fix the Pumps in 2006, 2007, and part of 2008, Westmoreland argues that company officials improperly "threw in the towel" by November 2008. Despite repeated warnings from the FDA that Baxter's remedial efforts were insufficient—warnings that were directly communicated to CEO Parkinson and passed along to the board of directors—the board took no action to ensure the company's timely compliance with the law, choosing instead to work on the new Sigma Pump despite its legal obligations regarding the old Colleague Infusion Pumps. This conscious disregard of Baxter's responsibilities under the Consent Decree and FDA regulations, Westmoreland continues, jeopardized the health of thousands of patients who relied on Colleague Infusion Pumps for their medical treatment and ultimately exposed Baxter shareholders to significant financial losses. Westmoreland argues that the directors' obstinacy "in the face of a clear mandate from the FDA to do more falls squarely into the category of behavior that is so facially egregious that, at the pleading stage, it creates a reasonable inference of bad faith and excuses demand."

The wrongdoing alleged in this case bears strong similarities to that challenged in *Abbott Labs*, where this court held that a board of director's failure to rectify ongoing violations of FDA regulations could constitute bad faith excusing demand. There, the shareholders filed suit against Abbott Labs' directors, alleging breach of fiduciary duty following a costly recall of adulterated diagnostic test kits manufactured by the company. According to the complaint, FDA officials conducted thirteen inspections of the company's manufacturing facilities over a six-year period, during which Agency officials repeatedly identified "current

good manufacturing practice" and "quality system regulation" shortcomings, see 21 C.F.R. Part 820, the same regulations at issue here. 325 F.3d at 799. FDA officials sent several "Warning Letters" over this period formally advising certain company officials of this noncompliance. *Id.* For two and a half years, the FDA and company officials worked together closely under a "comprehensive Voluntary Compliance Plan," but eventually the FDA "clos[ed] out the Compliance Plan" in the face of continued "deviations" by Abbott Labs from the regulations. *Id.* at 800. Six months later, the FDA filed suit, which the parties promptly resolved through a consent decree. The agreement barred Abbott Labs from manufacturing certain devices until independent experts and FDA inspectors certified that its facilities were in compliance with FDA regulations; required the company to withdraw certain products from the market; and obliged Abbott Labs to pay a $100 million civil fine. *Id.* at 801.

We concluded that these allegations created a reasonable doubt that the directors' actions fell outside the protection of the business judgment rule. *Id.* at 809. The directors "knew of the violations of law, took no steps in an effort to prevent or remedy the situation, and that failure to take any action for such an inordinate amount of time resulted in substantial corporate losses." *Id.* Emphasizing the "magnitude and duration of the alleged wrongdoing," coupled with significant evidence that the directors were "on notice" regarding the "current good manufacturing practices" violations, we concluded that there was a reasonable possibility of bad faith. Although we implied in *Abbott Labs* that "gross negligence" would establish a breach of the duty of loyalty under Delaware law—a standard that Delaware

courts have since refined—our reasoning was largely consistent with subsequent Delaware cases holding that when "directors fail to act in the face of a known duty to act, thereby demonstrating a conscious disregard for their responsibilities, they breach their duty of loyalty." *Stone*, 911 A.2d at 367, 370. We thus found that the pleadings were sufficient and that they alleged sufficient facts to excuse Abbott Labs' shareholders failure to make a pre-suit demand.

In some ways, the arguments for "bad faith," and thus for demand futility, are even stronger here. *Abbott Labs* did not involve any affirmative obligations imposed on the board of directors by virtue of a consent decree; there the directors faced potential personal liability simply for failure to rectify ongoing and known noncompliance with FDA quality-standards regulations. Westmoreland's complaint alleges not only that Baxter's directors consciously flouted the same FDA regulations, but also that the directors knowingly steered Baxter on a course that was all but certain to prompt the FDA to take enforcement action under the 2006 Consent Decree.[1] And in *Abbott Labs*, we had to infer

[1] When the FDA acted, it invoked its power under Paragraph 15 of the Consent Decree, which reads as follows in pertinent part: "If, at any time after this decree has been entered, FDA determines, based on the results of an inspection, sample analysis, a report or data prepared or submitted by Defendants, the Expert, or the Auditor pursuant to this decree, or any other information, that Defendants have failed to comply with any provision of this decree, or have violated the Act or its regulations, or that additional corrective actions are necessary to achieve compliance with this decree or the Act, FDA may, as and when it deems necessary, order Defendants in writing to take appropriate actions with respect to the Infusion Pumps or components thereof located in or to be distributed (continued…)

that the board was kept informed about the company's discussions with the FDA based on the responsibility of leading company officials to share such information with the full board. See 325 F.3d at 802, 809. Here, no such inference is necessary, since the complaint alleges particularized facts (*e.g.*, meeting dates and minutes) indicating that the directors were intimately involved in overseeing the remedial effort.

Despite these similarities, the district court thought *Abbott Labs* was distinguishable: it wrote that "Baxter's board *acted*, devoting substantial resources and attention over a prolonged period of time … to remediate the Colleague Pump problems," whereas in *Abbott Labs* the directors failed "to take *any action* concerning the problems over a six-year period." (Emphasis in original). Perhaps the problems with the Pumps were simply unfixable, it speculated, since Westmoreland's complaint did not specify "what the [d]efendants could or should have done differently." The district court concluded that Westmoreland's allegations that the remedial efforts were "minimal" and "deeply flawed" would establish at most that the directors "made poor decisions," but that they provided "no basis to believe that [the directors] were acting in bad faith."

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in the United States, including but not limited to, the following: [C]ease the manufacture, processing, … and interstate distribution of any or all the Infusion Pumps or components thereof[;] Recall … adulterated or misbranded Infusion Pumps …; and/or … Take any other corrective action(s) as FDA, in its discretion, deems necessary to protect the public health or to bring Defendants into compliance with the Act, its implementing regulations, and this decree."

There are at least three problems with this analysis. First, Westmoreland does not challenge the directors' actions from 2006 to 2008, when Baxter *was* devoting considerable resources to fixing the Pumps. Rather, Westmoreland contends that the directors breached their duty of loyalty when they made a conscious decision to *halt* these efforts in late 2008, despite clear and specific guidance from the FDA that additional action from Baxter was needed to bring the company into compliance with FDA regulations and the terms of the Consent Decree. In November 2008, Westmoreland alleges, the FDA informed Baxter that it needed to design and perform clinical trials in order properly to remedy the Colleague Infusion Pumps, but the company declined to do so. Instead, Westmoreland asserts, that was when it dramatically cut the amount it was spending on the remedial efforts. Baxter's earlier measures, however laudable, do not negate the possibility that its directors acted in bad faith during this later period.

Second, the district court incorrectly paints *Abbott Labs* as a case involving directors who took literally no action whatsoever in seeking to fix an adulterated product. Although it is true that we faulted Abbott Labs' directors for not "tak[ing] any action," that statement did not stand alone and cannot be taken literally. We also recognized that the company was party to a "comprehensive Voluntary Compliance Plan" with the FDA for almost half of the period of alleged wrongdoing. 325 F.3d at 809. The FDA eventually grew frustrated with Abbott Labs and "clos[ed] out" the Plan, but it acknowledged "Abbott Laboratories' efforts to meet all of the Compliance Plan commitments." *Id.*; see also *id.* at 802 (noting board of directors held 31 meetings during relevant period, during which directors presumably

discussed FDA compliance issues). The gravamen of the shareholder's complaint was not that Abbott Labs' directors did *nothing*, but rather that the defendants "knew of the continuing pattern of noncompliance with FDA regulations … and yet ignored repeated red flags raised by the FDA … and chose not to bring a prompt halt to the improper conduct causing the noncompliance," thus incurring severe penalties for the corporation. *Id.* at 802. We held that these allegations raised a sufficient possibility of bad faith to excuse demand. To the extent there are differences in the (similarly ineffectual) actions of Baxter's directors as portrayed in Westmoreland's complaint, they are small differences of degree, not kind.

Finally, the district court's focus on other hypothetical explanations for the defendants' conduct improperly ignores the rule that "any inferences reasonably drawn from the factual allegations of the complaint must be viewed in the light most favorable to the plaintiffs." *Abbott Labs*, 325 F.3d at 803. Indeed, as in a recent Delaware Court of Chancery case (where the court *rejected* a comparable Chancery Court Rule 23.1 motion to dismiss), it is altogether possible:

> that the directors received advice from sophisticated counsel … , understood where the boundary lay, and approved a business plan and management initiatives in the good faith belief that [the company] was remaining within the bounds of the law, although perhaps close to the edge … . If this scenario proves true, then [although demand was excused,] the directors will not have acted in bad faith and will not be liable to [the company] for any harm it suffered.

*La. Mun. Police Empls.' Ret. Sys. v. Pyott*, 46 A.3d 313, 356 (Del. Ch. 2012), reversed on other grounds, --- A.3d ---, 2013 WL 1364695 (Del. Apr. 4, 2013) (trial court should have given full faith and credit to California judgment). On the other hand, as Westmoreland suggests, it could be that the directors diverted critical resources to speed the development of the new Sigma pump, cynically gambling that this next-generation device could establish a market foothold, and that Colleague Infusion Pumps already in use would become obsolete before the FDA spotted Baxter's abandonment of its earlier efforts.

At the pleading stage, without the benefit of discovery, there is no way to "determine what actually happened." *Id*. This uncertainty is an unavoidable consequence of Delaware's demand futility rule. See *Starrels,* 870 F.2d at 1175-76 (Easterbrook, J., concurring) ("A final oddment in the *Aronson* approach [is that it requires] bobtailed adjudication, without evidence. If facts suggesting [a reasonable doubt] that the business judgment rule will not prevent recovery have come to light, the investor may plead them and litigate further, setting the stage for still another decision about the scope of the business judgment rule."). The important point is that Delaware's demand futility law does not require Westmoreland to "plead particularized facts sufficient to sustain 'a judicial finding[,]' … [n]or must [the complaint] demonstrate a reasonable probability of success." *Pyott*, 46 A.3d at 256. The proper inquiry is whether Westmoreland has made a sufficient "threshold showing, through the allegation of particularized facts, that [its] claims have some merit," *Rales v. Blasband*, 634 A.3d 927, 934 (Del. 1993). We conclude that Westmoreland's complaint meets that standard.

## IV

The development and manufacture of complex medical devices and pharmaceuticals is a risky business. Nothing we have said should be taken as a suggestion that officers and directors in these industries forfeit the protection of the business judgment rule simply because some initiatives fail. We hold instead that Westmoreland's complaint has cleared a significant hurdle. Delaware law is clear that "where the fiduciary intentionally fails to act in the face of a known duty to act, demonstrating a conscious disregard for his duties," such conduct establishes a failure to act in good faith. *Stone*, 911 A.2d at 369 (quoting *In re Walt Disney Co. Deriv. Litig.*, 906 A.2d 27, 67 (Del. 2006)); see also *In re Massey Energy Co.*, at *20 ("Delaware law does not charter law breakers."). Because the particularized facts that Westmoreland has furnished cast a reasonable doubt that the defendants' conduct was the product of a valid exercise of business judgment, *Aronson* 473 A.2d at 814, we REVERSE and REMAND for further proceedings.